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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,280	12/21/2000	Michinobu Nakamura	197748US0PCT	5123

22850 7590 05/29/2002

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EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/29/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/674,280	Nakamura et al.
Examiner	**Art Unit**
Vera Afremova	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *May 14, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*

Claim(s) objected to: *none*

Claim(s) rejected: *7-26*

Claim(s) withdrawn from consideration: *none*

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

Attachment to Advisory Action

The amendment filed 5/14/2002 under 37 CFR 1.116 in reply to the final rejection will be entered upon the filing of an appeal, but is not deemed to place the application in condition for allowance.

Response to Arguments

Applicants' amendments and arguments filed 5/14/2002 have been fully considered but they are not persuasive for the reasons below.

Applicants' main argument is directed to the idea of using a "submerged culture fermenter-type reaction vessel" which is usually used for culturing microorganism in an aqueous medium with aeration and agitation (see response page 4, par. 3). Upon review of the instant application and claims, it appears that the fermenter which is argued is not a vessel specially designed for the benefit for producing hydrolyzed protein with koji microorganisms (see specification page 24, par. 1) but rather it is a generic vessel which allows to hold a vegetable material and to culture microorganisms in a media comprising liquid and vegetable substrate as disclosed in the application or in an aqueous medium with aeration and agitation as argued. Moreover, applicants appear to admit that the claimed "submerged culture fermenter-type reaction vessel" is a vessel which is **usually** used for culturing microorganism in an aqueous medium with aeration and agitation (response page 4, par. 3, line 6). The device of the reference by Takebe et al. [US 6,045,819] is also a generic vessel which allows to culture koji microorganisms in a media comprising at least 40 % by weight of water (col. 9, line 63) and

vegetable substrate as disclosed. Further, the cited patent teaches aeration, stirring or agitation (col. 10, line 45-60) of the vegetable substrate inoculated with aerobic koji microorganisms. Applicants' argument that the disclosure related to the temperature changes during aeration and agitation in the vessel of Takebe et al. teaches away from the use of a "submerged culture fermenter-type reaction vessel" (response page 4, last par.) does not appear to have persuasive grounds because the temperature ranges are the same for both cited method and claimed method. For example: the cited method requires the use of temperature between 15-39 C (claim 7, step (3)) for the first stage of enzymatic hydrolysis in the process for producing hydrolyzed protein and the cited method teaches the use of temperature between 30-40 C for the first stage of enzymatic hydrolysis in the process for producing hydrolyzed protein. Therefore, regardless the fact that the cited patent does not clearly discloses the use of a "submerged culture fermenter-type reaction vessel", the vessel or device of the cited patent is reasonably considered to be suitable for culturing microorganism in an aqueous medium with aeration and agitation and/or for producing hydrolyzed protein by subjecting vegetable protein material to enzymatic hydrolysis with koji microorganisms.

With regard to the disclosure by Muller et al. [WO 95/28853] applicants argue that koji inoculum is prepared on "trays" rather than in "submerged culture fermenter-type reaction vessel". However, the claimed method is not limited to any amount of water content in "submerged culture fermenter-type reaction vessel" in order to obtain koji culture or fungal culture. Moreover, fungal cultures which are encompassed by the claimed invention are aerobic

fungal culture or koji molds and, thus, the fungal culture is reasonably expected to be provided with oxygen in order to grow rather than to be within an anaerobic system or to be totally "submerged" in the culture vessel. Therefore, a particular design of the vessel either it is a tray or a "fermenter-type reaction vessel" does not appear to be a critical element for at least initial possession of a fungal culture which is further used in the process for producing hydrolyzed protein by enzymatic hydrolysis of vegetable protein material with the fungal culture or koji microorganisms. Moreover, the reference by Muller et al. [WO 95/28853] teaches that steps drawn to enzymatic hydrolysis are conducted in a vessel/container after addition of fungal culture to a vegetable material which is characterized by "marked liquefaction" (see page 9, last paragraph and paragraph 2, line 3). Thus, the cited method is reasonably considered to encompass the use of a liquid system for hydrolyzing vegetable protein as intended by the applicants' method. The cited process is conducted within a "container" (page 9, line 7) which is reasonably considered to be substantially similar, if not identical, to a "submerged culture fermenter-type reaction vessel" as argued and claimed.

Therefore, the cited reference by Takebe et al. {US 6,045,819 [A]} and reference by Muller et al. {WO 95/28853 [N]} are considered to anticipate the claimed invention since the cited methods of US 6,045,819 [A] or WO 95/28853 [N] comprise identical active steps and identical structural elements as the claimed methods. Thus, the final product at the completion of identical reactions would inherently be identical.

In the alternative, even if the claimed method is not identical to the referenced methods of US 6,045,819 [A] or WO 95/28853 [N] with regard to some unidentified steps or structural elements or some characteristics of fungal cultures, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced methods are likely to inherently produces the same or substantially similar products at the completion of reaction/fermentation particularly in the light of teaching of US 3,655,396 [B], JP 50019996 [O] and/or Muramatsu et al.[U] which demonstrate that the use of koji mold preparation/fermentation in liquid or semi-liquid systems at the same temperature from 25°C to up to 60°C or temperature either 25-30°C or 55-60°C are characterized by the same amounts of reducing sugars produced from vegetable materials such as less than 5% as the claimed resulting preparation. In addition, the cited US '819 teaches that hydrolysis of vegetable proteins depends on a particular type of koji mold which is employed for hydrolysis (col. 14, line 29). And the claimed invention appears to employ an identical koji mold such as *Aspergillus oryzae* (see specification page 24) as the cited methods. Thus the claimed method would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of clear evidence to the contrary.

The comparative example in the applicants' specification is directed to a possession of a final hydrolyzed product which has a lower amount of reducing sugars as the result of practicing two stage fermentation when this two stage method is compared to one stage fermentation

without aeration in a liquid system (table 1 and 2) rather than to a criticality of a "liquid" system/fungal culture which is argued. All cited methods are two stage fermentations with aeration at least during first stage wherein. And the final products are characterized by amouts of less than 5% of reduced sugars as explained above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

May 23, 2002.

Irene Marx

IRENE MARX
PRIMARY EXAMINER